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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,561

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05/01/2006

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/764,561	Applicant(s) KATURA ET AL.	
	Examiner Karen E. Toth	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, drawn to an optical measurement apparatus.
 - II. Claims 5-10, drawn to a method of examining a patient for blood flow problems.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of invention II may be performed using a different apparatus than that of Invention I, such as one that does not use light irradiation to determine blood flow.
3. During a telephone conversation with Juan Marquez on 29 March 2006 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because:

(1) They fail to show element 21 in Figure 5 as described in the specification on page 6, lines 9-10.

(2) They fail to show elements 21 and 22 in Figure 4, as described in the specification on page 15, line 16, and page 16, line 1.

(3) They fail to show elements 21 and 22 in Figure 6, as described in the specification on page 16, lines 13-14.

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because:

(1) Reference character "1" has been used to designate a control computer (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(2) Reference character "2" has been used to designate a gas valve control device (Figure 1), a display element in Figure 4, and a display element in Figure 6

(3) Reference character "3" has been used to designate an air tank and valve (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(4) Reference character "4" has been used to designate a carbon dioxide tank and valve (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(5) Reference character "5" has been used to designate a gas mixer (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(6) Reference character "6" has been used to designate a gas concentration measurement device and valve (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(7) Reference character "7" has been used to designate a gas tube (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(8) Reference character "8" has been used to designate a mask (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(9) Reference character "9" has been used to designate a light measurement interface (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(10) Reference character "11" has been used to designate an optical interface (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(11) Reference character "12" has been used to designate an irradiating light interface clamp (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(12) Reference character "13" has been used to designate a light detection interface clamp (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(13) Reference character "14" has been used to designate a light irradiating guide (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(14) Reference character "15" has been used to designate a light detecting guide (Figure 1), a display element in Figure 4, and a display element in Figure 6.

(15) Reference characters "(a)" and "21" have both been used to designate the variation in the inhaled carbon dioxide signal (Figures 2 and 3).

(16) Reference characters "(b)" and "22" have both been used to designate the variation in the optical detection signal (Figures 2 and 3).

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: elements "X" and "Y", as shown in Figures 9 and 10.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b), are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

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corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: page 13, line 11 of the specification states, "as shown in FIG. 2A." Since Figure 2A does not exist, it is suggested that this be changed to --as shown by element (a) in FIG. 2--, since that appears to be what is referred to.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen'385 (US Patent Application Publication 2002/0169385) in view of Gorti'658 (US Patent 5954658).

Heinonen'385 discloses a system for measuring cardiac function (Figure 3) comprising means for controlling the content of carbon dioxide inhaled by a patient (paragraph [0034]) by using a carbon dioxide sensor (paragraph [0068]) and injection of carbon dioxide into the inhaled gas (paragraph [0070]) so that the body experiences simulated states of rest and tasks (paragraph [0017]); and a control unit for controlling the carbon dioxide states (element 70); wherein the system of Heinonen'385 measures the overall cardiac function of the patient. Heinonen'385 does not disclose using a light source and a light detector to irradiate the skin of the patient in order to measure blood flow in a specific area.

Gorti'658 teaches an apparatus for measuring blood flow comprising a light source (element 1) and a light detector (elements 5, 6, 7, and 12) that are used to scatter light off the skin of a subject and capture the reflected light, in order to measure the blood flow in a specific area.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the system of Heinonen'385 and added the specific measuring capabilities of Gorti'658, that is, a light source and detector, in order to measure blood flow in a specific area, for increased sensitivity and detailed analysis of patient condition.

Allowable Subject Matter

11. Claims 2-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the claimed structure as follows:

As to Claim 2, the prior art of record lacks the combination of light irradiation and detection sections, a carbon dioxide concentration control device, and a display showing variations in both carbon dioxide concentration and light detection over time.

As to Claim 3, the prior art of record lacks the combination of light irradiation and detection sections, a carbon dioxide concentration control device, and a display showing variations in a correlation between carbon dioxide concentration and light detection over time.

As to Claim 4, the prior art of record lacks the combination of light irradiation and detection sections, a carbon dioxide control device, and a computer that integrates to find a sensitivity distribution based on a combination of varied carbon dioxide concentration and measured light signals.

It should be noted that the closest prior art references are that of Heinonen'385 and Gorti'658. Heinonen'385 discloses a system that controls the concentration of carbon dioxide, but the system does not display variations in the concentration over time. Gorti'658 discloses a system that measures blood flow using light irradiating and

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detection sections, but the system does not display variations in the concentration over time.

In light of these typical prior art references, a thorough search of prior art failed to disclose any references or references which, taken alone in combination, taught or suggested a correlation or relationship between carbon dioxide concentration and light detection intensity as claimed.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2004/0144383 to Thomas et al, which discloses a system for controlling inhaled gasses.

US Patent 2099841 to Connell, which discloses an apparatus for administering gasses.

US Patent 6536429 to Pavlov et al, which discloses an apparatus for applying a breathing mixture.

US Patent 6577884 to Boas, which discloses an optical blood flow measurement apparatus.

US Patent 4166454 to Meijer, which discloses an optical cardiac monitor.

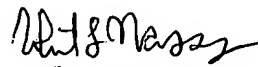
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EXAMINER